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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,240

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Yoshihiro Nagaoka

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06/26/2007

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EXAMINER

WRIGHT, PATRICIA KATHRYN

ART UNIT

PAPER NUMBER

1743

NOTIFICATION DATE

DELIVERY MODE

06/26/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/814,240	<b>Applicant(s)</b> NAGAOKA ET AL.	
	<b>Examiner</b> P. Kathryn Wright	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/2004; 10/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-9, in the reply filed on June 04, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).
2. Claims 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Priority***

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Drawings***

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "housing part",

"connection part", "sample channel", and "reaction region" in claim 1 must be shown or the features canceled from the claims. Similarly, the "first storing portion" and "second storing portion" in claim 3 must be shown or the features canceled from the claims. No new matter should be entered.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "12" has been used to designate both "motor" and "holding disc" see page 14 of the instant specification.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "20" and "30" have both been used to designate the "reagent cartridge" and "testing cartridge", see page 17, lines 6-18 of the instant specification.

8. The drawings are objected to under 37 CFR 1.83(a) because they fail to show reference character "2" (see page 14, line 17), reference characters "20" "30" in Fig. 5 (see page 19, lines 17-23). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

10. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words.

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Notice for example missing period at page 18, line 16 of the instant specification.

### ***Claim Objections***

12. Claim 5 is objected to because it sets forth "wherein a plurality of reagent cartridges are provided, and a first reagent cartridge...and a second reagent [sic] cartridge". Applicant should amend the claims to reflect the first and second reagent cartridges are part of the plurality of cartridges. Also, Applicant should correct the missed spelled "reagent" with --reagent--wherever present in the claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1 recites a "connection part". The Examiner is not sure what is meant by "connection part". Does Applicant mean an inlet port? Furthermore, the Examiner cannot find any features in the specification or figures that correspond to the "connection part". Clarification is respectfully requested.

Similarly, the Examiner does not understand what the "reaction region" in claim 1 is referring to. Is the reaction region the same as the reaction chamber 420 taught in the specification (see Fig. 14; page 25, line 25 of the instant specification)?

Furthermore, the claim 3 recites "a first reagent storing part" and "a second reagent storing part". It is not clear what Applicant is referring to. Are these storing parts the same as the reagent chambers (220, 230, 204, 250, 260) supported in the specification?

Claim 9 recites a "building up direction". What *direction* is a building up direction?

Claims 1-9 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are between the connection part and the channel cartridge.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kazlauskas et al. (US Patent No. 4,940,527), hereinafter "Kazlauskas".

Kazlauskas teaches a centrifuge 12 with detachable test cartridge structure 10 rotatably mounted within the housing part 14 (Fig. 1). The centrifuge rotor can accommodate at least ten test cartridge structures (col. 8, lines 55+). The test cartridge structure has a reagent portion 16 for storing reagent (see col. 4, lines 7-40) and "channel cartridge" or testing portion 18. The Kazlauskas cartridge structure also includes connection parts 84, 86 that connect the reagent portion to the testing portion. The testing cartridges also has a series of channels (see Fig. 3) through which the reagent(s) and sample flows when the reagent portion is attached to the testing portion. Moreover, the testing portion includes a reaction region 92 for detecting the reaction

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between the reagent(s) and sample. Kazlauskas also describes a reaction detecting mechanism 14 that is disposed outside of the housing structure (col. 5, lines 34-49).

Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., sample containing nucleic acid and a capturing reagent for capturing the nucleic acid) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

The reagent portion of Kazlauskas includes a first reagent and a second storing portion 34, 36, respectively. The aforementioned reagent storing parts communicate with the sample channel when the reagent portion and the testing portion are attached (col. 7, lines 5+).

Kazlauskas also provides reusable or disposable reagent portions, which during use, are disposed facing toward the testing cartridge in order to attach thereto. The testing cartridge is also provided with an inlet 76 into which sample can be injected. The inlet is covered with the reagent cartridge when attached to the testing cartridge (col. 4, lines 58+; see Fig. 3).

### ***Claim Rejections - 35 USC § 102/103***

17. Claims 4-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kazlauskas (US Patent No. 4,940,52).



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The teachings of Kazlauskas have been summarized previously, *supra*. Kazlauskas teaches the use of a plurality reusable or disposable reagent cartridges interchangeable with the testing cartridge. The Kazlauskas reference is silent as to the process of retaining a first reagent cartridge at a lower temperature than a second reagent cartridge before being attached to the centrifuge. Similarly, Kazlauskas is silent as to the process by which the testing cartridge is retained at a lower temperature than the reagent cartridge before attachment to the centrifuge and the volume of the first reagent cartridge being smaller than a volume of the second reagent cartridge is disclosed.

The aforementioned limitations are considered by the Examiner as product-by-process limitations that are not believed to impart distinctive structural characteristics to the final product since the claimed product appears to be the same or similar to that of the prior art, although produced by a different process.

A product-by-process claim is one in which a product is defined at least in part in terms of the method or process by which it is made. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). See MPEP 2113 [R-1].

The Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180

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USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with clear and convincing evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

### ***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No.11/493,751 (hereinafter '751). Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention as defined by the

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claims in the present application fully encompass the invention defined by the claims of the '751 application. Both applications claim an analyzer for holding a cartridge having at least one reagent region having at least one reagent container (or storing part) in communication with a reaction region via at least one channel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

20. No claims allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

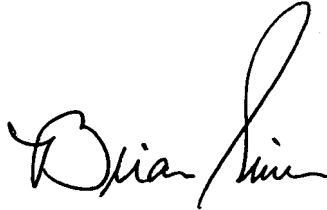
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 20, 2007

pkw

A handwritten signature in black ink, appearing to read "Brian Lin". The signature is fluid and cursive, with a large loop at the end of the last name.